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Randomised Prospective Study Of Comparision Of Post – Operative Motor Blockade And Pain Using Epidural Infusion Of 0.1 % Bupivacaine And 0.2 % Ropivacaine In Total Knee Replacament.

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Abstract: *Total knee replacement surgeries are painful for the first 12 to 24 hours and need good pain relief. We conducted a prospective, double blinded randomized study in 68 ASA I, II and III patients between 20- 70 years of age undergoing unilateral TKR surgery under spinal - epiduaral anaesthesia*

Aim- *To study and compare the VAS score, Motor blockade, by Bupivacaine and Ropivacaine for postoperative analgesia in TKR .*

Materials and Method- *Ethics committee approval and informed written consent taken. Patients were randomised, group A (0.1% bupivacaine) and group B (0.2% ropivacaine) with 34 in each group. Group A - epidural infusion of 0.1% bupivacaine and group B - 0.2% ropivacaine in the post operative period for 48 hours. Patients pain relief was assessed using VAS score and Motor blockade was assessed by Bromage scale*

Results-*Demographic data were comparable in both the groups. There was no statistically significant difference in the VAS score(at rest and on movements) in both the groups hence the post operative analgesia was comparable in both the groups.. Group B (Ropivacaine) had lower Bromage score compared to group A (Bupivacaine) on first post operative day. Motor blockade receded latter in Bupivacaine group than in Ropivacaine group.*

Conclusion- *The motor block is less intense and shorter lasting with Ropivacaine.*

Keywords: *Ropivacaine, Epidural, Motor Block,Total knee Replacement, Bupivacaine.*

I. Introduction

Patients undergoing Total Knee Replacement experience severe pain post operatively. Improved pain management techniques, surgical practices and the introduction of novel interventions have enhanced the Patient's postoperative experience after TKR [1]

Post-operative pain relief is an important aspect in management of TKR patients for early mobility and rehabilitation. Early mobilisation in this patients mandates an excellent pain relief and good motor activity after surgery. Anesthesiologist plays a important role of providing pain relief. Several different amide-type local anesthetics are currently available to provide satisfactory postoperative analgesia via the epidural route. Epidural analgesia is gold standard method used for post operative analgesia. Bupivacaine has been popularly used for decades now. Motor blockade , lower margin of safety, cardiotoxicity and neurological toxicity are common side effects. Ropivacaine is an S-enantiomer, having lesser degree and duration of motor blockade, cardio-neuro safe as compared to Bupivacaine. Ropivacaine has greater sensory-to-motor selectivity, less central nervous system and cardiac toxicity, a wider margin of safety, lower intensiveness, and lesser duration of motor block. [2,3]

Many studies have been done in TKR for post operative pain relief. Ours being a Teaching institute and government run hospital we get a different strata of high risk patients. It is very important to use safe drugs with lesser side effects in our sets of patients.

II. Material And Methods

In our study, we compared safety and efficacy of Ropivacaine and Bupivacaine used for postoperative epidural analgesia after TKR surgery. This was prospective, randomised double blind study conducted in KEM Hospital ,Mumbai during year 2011-2012. The purpose of the study was to compare quality of analgesia and motor blockade provided by the two drugs. Ethics committee approval and informed consent were obtained. 68 ASA grade I-III patients between age group 20 to 70 years scheduled for unilateral Total Knee Replacement (TKR) were included in this study. They were alloted to 2 groups by closed envelope method. Patients in Group A received Inj. Bupivacaine 0.1% via epidural infusion after TKR surgery and patients in group B received Inj. Ropivacaine 0.2% via epidural infusion. The nature of given the study and use of the VAS scale was explained

patients were taken in the OR. Basic monitors including pulseoximeter, cardioscope, and NIBP were attached. Baseline parameters were recorded. Epidural catheter was inserted in the L2-L3 space under all aseptic precautions either in sitting or lateral position as per patients convenience. Placement of epidural catheter was confirmed using loss of resistance to air and saline and positive meniscus sign. After confirming correct placement of epidural catheter subarachnoid block was given under same aseptic technique in L3-L4 space using 23 or 25 guage quinkes needle. After recession of sensory level by 2 segments, , epidural was activated with 3 ml of 2% lignocaine. Intraoperatively epidural bolus of 2-3 ml of 0.5%-0.25% bupivacaine was given as per requirement. Intraoperative vital parameters were recorded every 30 minutes . Epidural infusion of 0.1% Bupivacaine(GROUP A), or 0.2% Ropivacaine(GROUP B) was started at 5ml/hr after completion of surgery in an elastomeric easy pump. Epidural infusion was continued for 48 hours postoperatively during which period periodic monitoring of patients vitals i.e heart rate, blood pressure, along with VAS score at rest and movement, motor function score, nausea score recorded every hourly for 6 hours, and then every 6 hourly for 48 hours, or till the end point of infusion. The demand of rescue analgesia inj Diclofenac 75 mg IV was noted upto, 3 doses over 24 hours were given. Inj Tramadol 50mg was given for patients, where pain was not relived with inj Diclofenac.

Visual analog scale: 1 2 3 4 5 6 7 8 9 10

Modified Bromage Score:

Grade Definition

0 - No motor block

1- Inability to raise extended leg; able to move knees and feet

2- Inability to raise extended leg and move knee; able to move feet

3 -Complete block of motor limb

III. Result

Results of the study were observed and analysed statistically. The VAS score at rest and on movement , the motor function score ,side effects like nausea/vomiting ,and the heart rate and blood pressure were compared. Data was tested for normality and analysed using ANOVA test for numerical data and Chi Square test for categorical data. Statistical difference will be considered significant if $p<0.05$.

The mean age of the patients was comparable between the two groups with mean age in group A being 52.91 ± 11.91 and that in group B being 54.06± 7.59 years . The proportion of males and females was comparable between the two groups. Both the groups had equal distribution of ASA Grade I and II & III patients. Thus with respect to demographic variables both the groups were comparable. The mean baseline heart rate in group A was 90.24 ± 11.67 (Fig 1) beats per minute and in group B it was 84 ± 11.61(Fig 1) beats per minute respectively There was significant difference in the heart rate between two groups in the first five hours post operatively beyond which the heart rate in both the groups are comparable. This difference was statistically significant but not clinically The mean arterial pressure in both the groups were comparable. The baseline MAP was 91.47 ± 8.48 mm of Hg in group A and 89.89 ± 6.55 in group B. There was no episode of severe hypotension in either of the groups in the postoperative period.

VAS the pain score was noted at rest and movement at time intervals. VAS score at rest are comparable in both the groups(Fig 3). The VAS score on movement had significant difference on the first day with group B having lower VAS score as compared to group A with a mean VAS score falling from 5.09 to 3.56 (Fig 4)in group A whereas falling from 5.44 to 3.97(Fig 4) in group B in the first 12 hours. There is no significant difference in the VAS score on day 2 post operatively. The maximum VAS score achieved at rest was less than 5 in both the groups.Motor function was our secondary objective assessd using Modified Bromage Scale. There was a significant difference in the motor function score on the first postoperative day. Mean duration for recession of motor blockade to < 1 was 4 hours n group B and 6 hours in group A. The time to almost complete regression of motor blockade <12 hours in group B and >12 hours in group A. The Bromage score at 4,5 and 6 hours was 1.41 ± 0.66,1.38 ± 0.652, 0.94 ± 0.74(Fig 5) for group A and 0.91±0.621, 0.62 ± 0.551, 0.32 ± 0.48(Fig 5) for group B respectively. Demand of rescue analgesia was higher in Group b(Ropivacaine)

IV. Discussion

Total Knee Replacement is life style modification surgery but a painful procedure and requires good post operative pain relief .Poor control of post operative pain after TKR surgery may cause a series of adverse events that could negatively influence functional recovery and final result. [4]

Early mobilisation of post TKR patients have shown to reduce the incidence of thromboembolism and prevent nosocomial infection . Various studies have proven early mobilisation helps to reduce the stay in hospital[5] ,which decreases the bed occupancy rate. Multidisciplinary action[6] is key to enhance recovery in TKR patient and inadequate pain relief will results in delayed recovery and stress to patients Bupivacaine is commonly used in various studies in varying concentration for pain relief. [7,8] Ropivacaine is now frequently

used as an alternative to bupivacaine. Ropivacaine is a long-acting regional anaesthetic that is structurally related to Bupivacaine. It is a pure S(-)enantiomer, unlike Bupivacaine, which is a racemate[9]. Several studies are done in past to find optimum and effective concentration of Ropivacaine. The optimal concentration of ropivacaine when used alone for epidural analgesia is 2 mg/mL[10,11,12]. It is, a less toxic homolog of bupivacaine proved to be less cardio and neuro toxic[13,14]. Better safety profile and less motor blockade provided by Ropivacaine makes it the drug of choice in post operative epidural infusion[13,15,16].

In our study the VAS score at rest were not statistically significance in both the groups. The VAS score on movement have significant difference on the first day with group B having lower VAS score as compared to group A with a mean VAS score falling from 5.0 to 4.56 in group A whereas falling from 5.44 to 3.97 in group B in the first 12 hours. There is no significant difference in the VAS score on day 2 postoperatively. Bupivacaine gives better pain relief than Ropivaciane. Similar conclusion were observed by Muldon et al, in there study Ropivacaine group had higher VAS scores >30 mm at restand on movement during 8-24 hours post surgery, than in the bupivacaine group. Over the 24 hour infusion, the estimated difference in wound pain at rest was 5.6mm(p=0.017) and on passive movement 11.6mm(p=0.016). Scale used for VAS score was 0-100 mm in their study[17].

Kampe, Kanis and Diefenbach used epidural analgesia with 0.2% ropivacaine and 0.1% ropivacaine in combination with 1ug/ml of sufentanyl and concluded that there was no significant difference in VAS score between the two groups. Both groups provided effective post op analgesia with only minimal supplementation of PCA opiod[18]. Pitimana aree et al compared epidural (0.0625%) BF group (bupivacaine with fentanyl.3ug/ml) and R group (ropivacaine,0.15%) for post operative analgesia in TKR found that overall pain at rest and on movement was not significantly different in the two groups. Patient satisfaction was better in BF group[19]. In our study, there was no statistically significant difference in the VAS score(at rest and on movements) in both the groups hence the post operative analgesia is comparable in both the groups. Higher demand of rescue analgesia was seen in Ropivacaine group than Bupivacaine group patients, which proves better quality of pain relief in Bupivacaine group.

The motor function score in our study was significantly different in the immediate postoperative period in the two groups. Group B (Ropivacaine) had lower Bromage score compared to group A (Bupivacaine). It took more time for the motor blockade to recede in Bupivacaine group than in Ropivacaine group .In a study conducted by Muldoon and Milligan compared epidural analgesia between ropivacaine and bupivacaine, in the ropivacaine group, 50% of patients compared with 19% in bupivacaine group had no motor block 2 hours after operation, increasing to 88% of patients for ropivacaine and 56% for bupivacaine by 24hrs[17]. Ropivacaine is less lipophilic than bupivacaine and is less likely to penetrate large myelinated motor fibres; therefore, it has selective action on the pain-transmitting A δand C nerves rather than Aβ fibres, which are involve in motor function[20].

Ropivacaine produced significantly less motor, with the greatest difference seen in the lower concentration loading dose of ropivacaine[21]**-.** Motor block caused by Ropivacaine was of shorter duration than that caused by bupivacaine when given by epidural infusion was observed by Zaric D et al[22]. This suggests that continuous postoperative epidural ropivacaine infusion may permit early ambulation with greater margin of safety.. Kanai,et al found that Bromage score was higher in 0.2R group than in 0.125B group, the motor blockade gradually decreased, resulting in little difference between the groups where he compared**,** 0.1% ropivacaine(0.1R), 0.2% ropivacaine(0.2%R), and 0.125% bupivacaine(0.125 B) for post operative epidural analgesia in lower limb orthopaedic surgery[23].

No major side effects were seen throughout the study. Ours being a government run hospital, the strata of high risk patients, low socio economic condition and less education mandates use of drugs with fewer side effects. The early mobility of patients in Ropivacaine decreases the dependency on support staff in our set up.

V. Conclusion

We conclude that epidural 0.1% Bupivacaine and 0.2% Ropivacaine are comparable in terms of post operative analgesia and hemodynamics ,However the demand of rescue analgesia was higher with Ropivacaine group. The motor block is less intense and shorter lasting with Ropivacaine. Shortcoming of our study- The number of study patients should be more for better knowledge of complication with the drugs used. One more group of opoid with Ropivacaine should have been added to assess quality of pain relief.

Figures

Figure 1- Comparision of Heart Rate between Group A and B

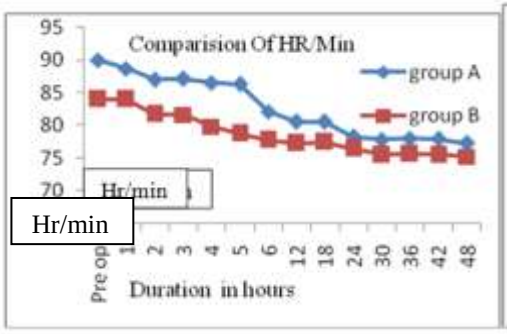


Figure 2 – Comparision of Mean arterial Pressure(MAP) between Group A and B

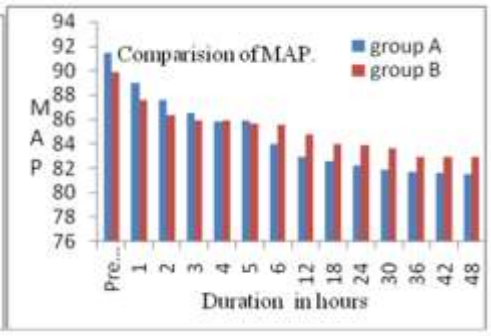


Figure 3 – Comparision of VAS Score at Rest.

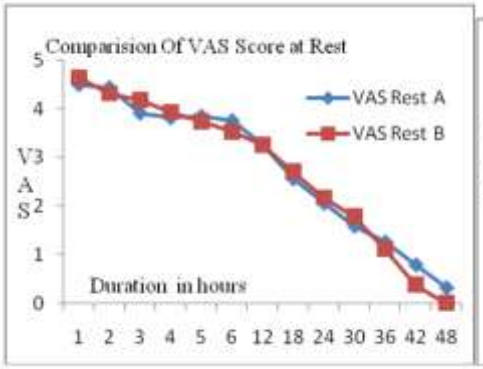


Figure 4- Comparision of VAS score on Movement.

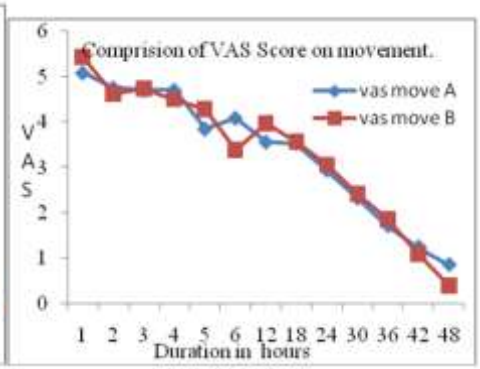
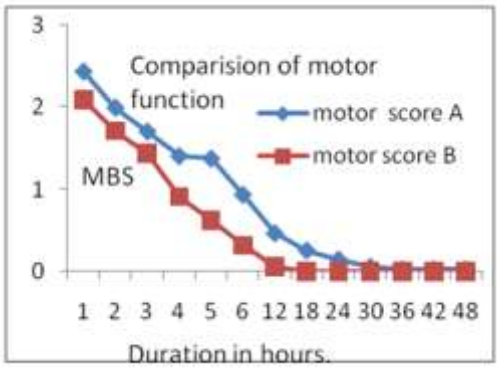


Figure 5-Comparision of Motor Function.

,MBS- Modified Bromage scale.



Bibilography

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